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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,613	07/11/2006	Seiichiro Miyahara	DK-US065158	8526
22919	7590	02/17/2010	EXAMINER	
GLOBAL IP COUNSELORS, LLP 1233 20TH STREET, NW, SUITE 700 WASHINGTON, DC 20036-2680				BOWERS, NATHAN ANDREW
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
02/17/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,613	MIYAHARA, SEIICHIRO	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-7,10 and 11 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-7,10 and 11 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>091609</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 20040029266) in view of Copeland (US 6429008) and Hesse (US 4336329).

Barbera-Guillem discloses a temperature control device for culturing fungi at a predetermined culturing temperature. Cells are grown within a cassette (Figure 1:100) that holds a culture medium. Paragraph [0327] states that the cassette is positioned adjacent to a Peltier device (Figure 89:1060) and conductor plates (Figure 89:1070) that both heat and cool the cassette. Control electronics (Figure 91:1055) include both a temperature setting unit and a temperature control unit configured to control the operation of the Peltier device. Figure 91 indicates that a communication unit (1000) is further provided for accommodating a plurality of cassettes such that each cassette is in communication with other cassettes. Although the Peltier devices of Barbera-Guillem are capable of functioning as both a heating mechanism and a cooling mechanism, Barbera-Guillem does not expressly state that both heating and cooling mechanisms are simultaneously provided for each cassette.

Hesse discloses a container (Figure 1:10) for culturing fungi at a desired temperature. Column 4, lines 6-26 state that both heater elements (Figure 2:13) and cooling coils (Figure 2:14) are provided to affect the temperature within the container.

Barbera-Guillem and Hesse are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to ensure that each cassette disclosed by Barbera-Guillem is in communication with at least one heating

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mechanism and at least one cooling mechanism. As evidenced by Hesse, this configuration is functionally equivalent to the use of a single Peltier element serving dual heating and cooling functions. One of ordinary skill would have recognized that the simultaneous provision of heating and cooling mechanisms would have allowed for quick and precise temperature change.

The combination of Barbera-Guillem and Hesse still differs from Applicant's claimed invention because Barbera-Guillem does not disclose a specific temperature range.

Copeland discloses a cassette for culturing fungi comprising a temperature control system. Column 14, lines 11-18 indicate that temperatures between 20 and 45 degrees Celsius allow for the efficient growth of most fungal cells.

Barbera-Guillem and Copeland are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to ensure that each cassette disclosed by Barbera-Guillem is maintained at temperatures between 20 and 45 degrees Celsius. More specifically, one of ordinary skill in the art would have been motivated to periodically switch between 27 degrees Celsius, 30-32 degrees Celsius and 35-37 degrees Celsius based on the immediate needs of the growing cells. It is well within the purview of one of ordinary skill to identify through routine experimentation the most desirable individual temperatures within a localized temperature range described by the prior art as suitable for cell growth.

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2) Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 20040029266) in view of Copeland (US 6429008) and Hesse (US 4336329) as applied to claim 1, and further in view of either Ammann (US 20020098117) or Butts (US 6518059).

With respect to claims 3 and 5-7, Barbera-Guillem, Copeland and Hesse disclose the apparatus in claim 1, however Barbera-Guillem does not expressly describe the relationship between each cassette and the provided control units.

Ammann discloses a plurality of temperature control devices (Figure 3:600, 602, 604, 606) in the form of incubators. This is described in paragraphs [0249]-[0251]. The heating devices, temperature sensors, and control system described in paragraphs [0260] and [0262] are fully capable of ensuring that each incubator is maintained at temperatures of 27 degrees Celsius and within the range of 30 to 32 degrees Celsius. The disclosed control system is additionally capable of being programmed to switch between two different temperatures at predetermined intervals over a designated time period. Ammann additionally states in paragraph [0262] that each incubator is connected to a control device. The temperature sensors and electrical connectors disclosed by Ammann are considered to be communication units that serve to link the incubators with the control device. Although Ammann does not expressly state that a specific incubator is used to control the others, any of the Ammann incubators are fully capable of being evaluated so that information from that specific incubator is used to control the operation of the other incubators. This is due to the fact that the controller of Ammann is fully capable of being programmed to consider any information (such as a

sensed condition within a specific incubator) when determining the protocol for all other incubators.

Butts discloses a plurality of temperature control devices (Figure 5:10, 100) each capable of accommodating a cell culture. This is described in column 4, lines 20-49. Each temperature control device includes a heater (Figure 5:42, 104) fully capable of maintaining a first temperature of 27 degrees Celsius and a second temperature of 30 to 32 degrees Celsius. Butts additionally states in column 3, lines 50-54 that each incubator is connected to a control device (Figure 4:36). The temperature sensors (Figure 5:38) and electrical connectors (Figure 5:14) disclosed by Butts are considered to be communication units that serve to link the incubators with the control device. Furthermore, Butts teaches in column 4, lines 20-49 that a master incubator is used to control the others so that detected information from every other incubator is sent to the master incubator.

Barbera-Guillem, Ammann and Butts are analogous art because they are from the same field of endeavor regarding incubator control systems.

At the time of the invention, it would have been obvious to arrange each individual cassette and control unit disclosed by Barbera-Guillem according to the configuration set forth by either Ammann or Butts. As evidenced by Ammann and Butts, it is well known in the art to control the temperature of a specific incubator independently from a plurality of other incubators operating simultaneously. Alternatively, Ammann and Butts also indicate that it is well known to provide controller

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configurations wherein the operation of a plurality of incubators is controlled by a single (master) incubator, which is in turn controlled by a control unit.

With respect to claim 4, Barbera-Guillem, Copeland, Hesse and Ammann/Butts discloses the apparatus in claim 3. Ammann additionally discloses in paragraph [0257] and Figure 22 that each incubator temperature control device comprises a plurality of internal testing locations (i.e. addresses) along the periphery of a carousel assembly. Paragraph [0259] states that the controller is used to regulate the rotation of the carousel, and thereby manage the position of the testing locations (i.e. addresses) within each incubator.

Response to Arguments

Applicant's arguments filed 10 December 2009 with respect to the 35 U.S.C. 102 rejections involving Ammann and Butts have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Barbera-Guillem, Copeland and Hesse.

As set forth in the rejections above, Barbera-Guillem indicates that it is known in the art to use a plurality of cassettes to culture fungi using heating/cooling elements and a temperature setting control unit. Hesse further states that the simultaneous use of individual heating elements and cooling elements is well known in the art. Copeland

additionally teaches that one of ordinary skill would have known to culture fungal cells at any specific temperature within the range of 20-45 degrees Celsius.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797